4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2006-D-0409] (formerly 2006D-0169)

Guidance for Industry: Guidance on the Labeling of Certain Uses of Lecithin Derived From Soy Under Section 403(w) of the Federal Food, Drug, and Cosmetic Act; Withdrawal of Guidance

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; withdrawal.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the withdrawal of a guidance entitled "Guidance for Industry: Guidance on the Labeling of Certain Uses of Lecithin Derived From Soy Under Section 403(w) of the Federal Food, Drug, and Cosmetic Act," dated April 2006, that was announced in the Federal Register on May 2, 2006. The guidance explained FDA's then current thinking on the labeling of certain uses of lecithin derived from soy under the Federal Food, Drug, and Cosmetic Act (the FD&C Act) and was part of FDA's implementation of the Food Allergen Labeling and Consumer Protection Act (FALCPA). We are taking this action because the policy stated in the guidance regarding FDA's consideration of the exercise of enforcement discretion no longer reflects our current thinking.

DATES: The withdrawal is effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER.]

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION: In a notice published in the Federal Register of May 2, 2006 (71 FR 25844), we announced the availability of a guidance entitled "Guidance on the Labeling of Certain Uses of Lecithin Derived From Soy Under Section 403(w) of the Federal Food, Drug, and Cosmetic Act." The guidance explained that, consistent with the need to establish enforcement priorities, we would consider the exercise of enforcement discretion for a food labeled on or after January 1, 2006, in which lecithin derived from soy is used solely as a component of a release agent and the label for such food does not declare the presence of soy consistent with the requirements of section 403(w) of the FD&C Act (21 U.S.C. 343(w)). In that guidance, the term "release agent" referred to an agent used to facilitate the release of foods from food contact surfaces, where the agent has been applied directly to the food contact surface, rather than incorporated into the food. In that guidance, we also stated our intention to reconsider our enforcement priorities with regard to the labeling of lecithin derived from soy used as a component of a release agent approximately 18 months after the issuance of the guidance. Further, we stated our expectation that, during the period in which we considered the exercise of our enforcement discretion, manufacturers of foods that use lecithin derived from soy as a component of a release agent would revise as necessary the labels of their relevant food products to comply with FALCPA and begin to label their products using the FALCPA-compliant labels by the end of the enforcement discretion period.

We believe that there has been sufficient time for all manufacturers of foods that use lecithin derived from soy as a component of a release agent to revise the labels for such foods to

be consistent with the requirements of section 403(w) of the FD&C Act. Therefore, we no longer believe it is appropriate to consider the exercise of our enforcement discretion with regard to foods that use lecithin derived from soy as a component of a release agent. For these reasons, we are withdrawing the April 2006 guidance entitled "Guidance on the Labeling of Certain Uses of Lecithin Derived from Soy Under Section 403(w) of the Federal Food, Drug, and Cosmetic Act."

Dated: February 19, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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